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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,455	05/09/2001	Arthur J. Blume	2598-4004US1	5124

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/852,455	BLUME ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *2,3,13-14, 17-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-12,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/23/04 has been entered.

Status of Claims

Claims 1-56 are pending in the application.

Claims 2-3, 13-14 and 17-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species.

Claims 1, 4-12 and 15-16 are under examination.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-12 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action, 3/23/04.

Response to Arguments

Applicants argue that in the last paragraph of page 4 of the specification, the US. Patent No. 5,877,077 (the '007 patent) is referenced and incorporated by reference. Example 5 of the '007 describes precursor peptides in relation to the human insulin receptor. In addition, applicants cite Principles of Biochemistry. A text that is well known to one skilled in the art. It discusses the state of protein synthesis e.g., folding and processing. It specifically recites that before or after folding the new polypeptide may undergo enzymatic processing to remove one or more amino acids.

In reply, the instant claimed invention does not recite for any named or structured compound for skill in the art to ascertain the claimed precursor. A precursor, as shown by the cited prior art is only determinable given the structure or

formula of a compound, not a compound with no given structural formula, as claimed. As stated by applicants in the instant REMARKS, page 3, paragraph one, "it is well within the ability of one of ordinary skill in the art to fully understand the structure of and to identify a binding partner precursor". (Emphasis added.) Furthermore, as evident from the cited textbook and the passage quoted therein, it appears that these precursors relate to post-processing of the protein. The claims do not recite for a post processing. Given no structural formula it is not readily apparent, which portions of the generic claimed unstructured polypeptide folding occurs for enzymatic processing to occur. The precursor disclosed in the cited prior art appears to be used in a different context to that being claimed. There are just too numerous, general ways by which said modifications can be made, as applicants recognized. Furthermore, the statement as to the different post-translational modifications, are nothing more than arguments, not supported in the as-filed specification. As argued, the modifications ***include*** only some modifications. But does not preclude some other modifications such as substitutions, deletions, additions of the post-translationally modified peptide, singly or in combinations.

Accordingly, the specific written description for the naturally occurring binding partner would not be adequate for the (incompletely) disclosed precursor. At the time of applicants' invention, it appears that applicants are not in possession of the generic claimed invention. See University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicants argue that the first page of the Blume publication clearly indicates that the first publication was online in February of 2001 and that the copyright year was 2001 not 2000. The 2001 publication date is confirmed by the e-mail from Steve Drew, which states that the publication was actually released to the public on February 6, 2001. Thus applicants assert that the Blume article was not available to the public before the priority date of May 9, 2000. In view of the above

arguments, the rejection of the claims under this statute is withdrawn.

Claims 1, 4-5, 9-12 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ivanenkov et al (The Journal of Biological Chemistry, 6/16/95).

Ivanenkov discloses at, e.g., page 14653, paragraph bridging columns 1 and 2 up to page 14654, column 1 and page 14656, under the heading Discussion up to page 14657, discloses a method of identifying a naturally occurring protein e.g., CapZ from a peptide containing a consensus sequence of the S-100b by comparing the consensus peptide sequence (motif, as claimed) obtained from a phage random library with the peptide structures present in a protein sequence databank, specifically Gen Bank. Ivanenkov discloses that in comparing these sequences a novel protein can be identified as based on the information regarding its binding interactions. Ivanenkov discloses at page 14653, paragraph bridging col. 1 and col. 2 up to page 14654, that n addition to aligning sequences of individual S-100b binding peptides with each other, naturally occurring proteins possessing sequences similar to the obtained consensus motif of S-100b binding peptides were determined. Such determination was done by comparing the binding peptide isolates (Table 1) with

structures in GenBank using BLAST. Several modifications (reads also on the claimed precursor) were applied that identifies the natural protein actin capping protein ACP, CapZ (Table II). The claimed precursor will also read on Ivanenkov description of proteolytic fragmentation of various S-100 target proteins, isolation and characterization of S-100 binding peptides from these proteolytic soups might permit the identification of consensus S-100 binding epitopes within the different S-100 targets (page 14652, col. 1). Accordingly, the specific method steps of Ivanenkov using specific components fully meet the broad claimed method. [Note that the rejection of the claimed precursor is based on applicants' REMARKS, above.]

Claims 1, 4-5, 9-12 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kraft (The Journal of Biological Chemistry, 1/22/1999) for reasons advanced in the last Office action. [This rejection was based on the natural proteins and not to its precursor.]

Response to Arguments

Applicants urge that the claims do recite the need for biological relevance and claim 1 does require that the gene product posses the motif be identified as the naturally occurring binding partner. It is argued that the statement in Kraft that "the possible biological relevance of such homologies

remains unknown" runs directly counter to the above stated limitation of claim 1. It is further argued that the evidentiary support for the conclusory statements is present in Kraft itself. That the DLxxL peptides do not compete for the β6 binding site on the αv chain is found at page 1984, right column, line 14. It is argued that Kraft reports that the motifs identified do not look like the naturally occurring binding partner fibronectin. It is finally argued that in the last paragraph of the discussion, Kraft concludes that at present we have no indication, where, if at all, the XX-DLxxLx sequences play a biological role with αvβ6 integrin. Clearly, Kraft et al is argued, by their own statements, do not believe they have found a naturally occurring binding partner.

In response, Kraft clearly states that this is a naturally occurring binding partner as the motif is obtained from a natural binding protein. Kraft states that the biological relevance of such homology of αvβ6 is not known. However, the peptide binding effect is known to be inhibitory of the natural ligand (from which the peptide was obtained that inhibits binding to its natural partner). Kraft discloses that it is the homologous relevance of the different non-previously unidentified compounds that do not have a biological significance i.e., a further identification of the other

substances that can bind to the motif. However, the motif itself is known to bind to a naturally occurring partner in addition to the found homologous compounds. Kraft states "….FASTA search of the GEMBL databases revealed several-extracellular matrix components related consensus sequences…including fibrinogen…With the exception of tenascin, which has been reported to bind in an RGD-dependent way to…αvβ6, none of these molecules has been implicated previously as a ligand for αvβ6, thus, the possible biological relevance of such homologies remains unknown…". (Emphasis added.) [It is of interest to note that the claims simply recite that the gene product identified as the naturally occurring binds to a partner. It does not equate such binding to a biological significance especially for the non-structured compound as instantly claimed.]

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft or Ivanenkov in view of Kay et al (6,303,574) for reasons of record.

Ivanenkov is discussed above. Ivanenkov does not disclose a random sequence comprising about 20-40 amino acids or consists essentially of the 20-40 residues. Kay discloses at col. 5, lines 20-63 a random sequence of 9-45 amino acid residues encompassing a consensus sequence. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add flanking sequences to a consensus sequence of Ivanenkov in the manner as taught by Kay. Adding such flanking sequences in a consensus sequence provides random sequences or motifs that reflect variations in the motif domain binding selectivities or specificities, as taught by Kay. This would provide the motivation to one having ordinary skill in the art to expand or produce a longer length random peptide to locate and fingerprint the motif with high specificity and selectivity.

Response to Arguments

Applicants' arguments with respect to Kraft will be applied to Ivanenkov as well. Applicants urge as argued above, Kraft does not teach identifying a naturally occurring binding

partner, nor does Kay. In the Examiners response to the Applicants' arguments it is stated that Kay is relied on to support that the length of the random peptide can be varied. Applicants submit that Kay does not remedy the lack of disclosure of a naturally occurring binding partner in Kraft. In addition, the Examiner has not cited a motivation for combining Kay with Kraft. Since neither reference teaches identifying a naturally occurring, binding partner, Applicants assert that there is no motivation to combine. As neither Kraft or Kay, alone or in combination, teach the identification of a naturally occurring binding partner.

In response, as stated in the last Office action, even without Kay, Kraft's disclosure of a peptide of 6-12 residues or Ivanenkov's 15-residue random peptide approximates the claimed of ***about*** 20 to 40 amino acids. About is a warning that exactitude is not claimed but rather a contemplated variation. About is entitled to latitude in characterizing feature, which was not critical to distinction over prior art. General Foods v. Perk Foods Co., 157 USPQ 14. The motivation in combining these references was provided in the Office action of 1/29/03 and above under the Ivanenkov.

In view of applicants' arguments the rejection of the claims under 35 USC 112, second paragraph no longer applies.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0812. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
December 13, 2004